

## REMARKS

### Summary of Office Action

Claims 1-7, 9-16, and 18-27 were pending in this application. Claims 22-27 were withdrawn from consideration pursuant to a restriction requirement.

Claims 1, 2, 7, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kruck U.S. Patent No. 3,974,832 (hereinafter "Kruck"). Dependent claims 3-6 were rejected under 35 U.S.C. § 103(a) as being obvious from Kruck.

Claims 10-16 and 18-21 were rejected under 35 U.S.C. § 103(a) as being obvious from Kruck in view of Sarnoff et al. U.S. Patent No. 4,755,169 (hereinafter "Sarnoff").

### Summary of Applicant's Reply

Applicant has amended the specification to correct two reference number typos.

Applicant has amended independent claim 1 to more precisely define the invention. Independent claim 10 has been amended to include the limitation of dependent claim 16, which has been amended to more precisely define the structural relationship between the elements. And new dependent claims 28 and 29 have been added.

No new matter has been added.

Reconsideration of this application in view of the amendments and following remarks is respectfully requested.

Rejections of Claims 1-7 and 9 Under 35 U.S.C. §§ 102(b) and 103(a)

Claims 1, 2, 7, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kruck. Dependent claims 3-6 were rejected under 35 U.S.C. § 103(a) as being obvious from Kruck.

These rejections are respectfully traversed.

Amended independent claim 1 requires, among other things, that the wall of the needle-supporting portion be adjoined on its exterior surface by the second hub portion and adjoined on its interior surface directly opposite the adjoined exterior surface by the first hub portion so as to form a contiguous, mutually reinforcing sandwiched structure of the second hub portion, the wall, and the first hub portion. Support for this amendment is found in applicant's specification on, e.g., page 7, paragraph 30: "As can be seen most clearly in FIGURE 4, the needle-supporting end 50 ... is essentially 'sandwiched' between the first and second molded hub portions 42, 44. That positioning of the needle-supporting end 50 ... between the first and second molded hub portions 42, 44 is mutually reinforcing and adds to the rigidity of the overall structure."

Kruck's hypodermic needle assemblage does not meet this requirement.

As shown in Kruck's FIG. 1, hub shoulder 56 of hollow key member 48 ( $\approx$  the first hub portion) contacts internal shoulder 40 ( $\approx$  the wall) of ferrule 26 ( $\approx$  the cap). However, flange 52 of cup portion 46 ( $\approx$  the second hub portion) does not contact ferrule 26 directly opposite internal shoulder 40 of ferrule 26 -- there is a gap between ferrule 26 and flange 52.

Similarly, at upper surface 58 of ferrule 26 where flange 52 contacts ferrule 26, hollow key member 48 does not contact ferrule 26 directly opposite upper surface 58 -- there is empty space on the opposite side of upper surface 58 where flange 52 contacts ferrule 26.

The same holds true for hub shoulder 54, internal shoulder 38, and flange 50 on the left side of Kruck's needle assemblage as shown in FIG. 1.

Thus, there is no area or even a point where Kruck's cup portion 46 ( $\approx$  the second hub portion), internal shoulders 38, 40 ( $\approx$  the wall), and hollow key member 48 ( $\approx$  the first hub portion) adjoin directly opposite each other to form a contiguous, mutually reinforcing sandwiched structure as required by applicant's claim 1.

Kruck therefore does not anticipate independent claim 1, which should now be allowable.

For at least these reasons, dependent claims 2-7 and 9, which depend directly or indirectly from independent claim 1, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Moreover, dependent claim 7 requires that the reinforcing structures be radially-extending ribs. See, e.g., applicant's FIG. 5D, which shows radially extending ribs 66. Kruck has no such reinforcing structures, as shown in Kruck's FIGS. 1, 5, and 6, which show flanges 50 and 52 extending from the base of cup portion 46 ( $\approx$  the second hub portion), but no ribs as defined and described by applicant. Thus, dependent claim 7 is also not anticipated by Kruck for that reason.

Accordingly, applicant respectfully requests that the rejections of claims 1-7 and 9 under 35 U.S.C. §§ 102(b) and 103(a) be withdrawn.

Rejections of Claims 10-16 and 18-21 Under 35 U.S.C. § 103(a)

Claims 10-16 and 18-21 were rejected under 35 U.S.C. §103(a) as being obvious from the combination of Kruck and Sarnoff.

These rejections are respectfully traversed.

Independent claim 10 has been amended to require that the reinforcing structures be radially-extending ribs. As discussed above with respect to dependent claim 7, Kruck has no such reinforcing structures. Moreover, Kruck has no need for radially-extending ribs because Kruck's needle assemblage is for a hypodermic needle and not an automatic injector. In contrast to the low stresses under which a hypodermic needle is typically used, the ribs "act to stabilize and reinforce the needle-supporting end 50 ... and prevent it from warping, distorting, or otherwise deforming due to the stresses encountered during automatic injection" (applicant's specification, page 9, lines 4-6).

Accordingly, claim 10 is neither anticipated by nor obvious from Kruck.

The Examiner contended that it would have been obvious "to use the stored energy means of Sarnoff with the hub assembly of Kruck in order to provide a means for automatically injecting a medicament into a patient ... (i.e., by allowing the stored energy means to provide force to the plunger)." February 19, 2008 Office Action, page 4.

Applicant submits that Sarnoff does not make up for the structural deficiencies of Kruck and further submits that Kruck may not work with an automatic injector because "the inner end of the needle 24 ... pierces the sealing membrane 18" (Kruck, col. 4, lines 20-22) as Kruck's needle assemblage is mounted to syringe barrel 12. That is, sealing membrane 18 is pierced before activation of an automatic injection process. A liquid medicament may thus leak

out through the needle as the injector is carried, handled, and positioned prior to activation. Recall that the purpose of automatic injectors is to provide quick administration of a medicament often in emergency situations. Therefore, to delay mounting of the needle assemblage until the injector is needed, or to risk some or all of a liquid medicament leaking out through the needle before activation, is unacceptable for an automatic injector.

Accordingly, the combination of Kruck and Sarnoff may not result in a practical device without significant redesign and, in any case, does not render obvious amended independent claim 10, which should now be allowable.

For at least these reasons, dependent claims 11-16 and 18-21, which depend directly or indirectly from independent claim 10, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Moreover, dependent claim 16 requires that the wall of the needle-supporting portion be adjoined on its exterior surface by the reinforcing structures and adjoined on its interior surface directly opposite the adjoined exterior surface by the first hub portion so as to form a contiguous, mutually reinforcing sandwiched structure of the reinforcing structures, the wall, and the first hub portion. As discussed above with respect to claim 1, Kruck's hypodermic needle assemblage has no such structures. Thus, dependent claim 16 is also not obvious from the combination of Kruck and Sarnoff for that reason.

Accordingly, applicant respectfully requests that the rejections of claims 10-16 and 18-21 under 35 U.S.C. §103(a) be withdrawn.

New Dependent Claims 28 and 29

New claims 28 and 29 are supported in the specification at, for example, page 8, paragraph 31, lines 6-9: "The needle 46 extends to a stop 58a .... The stop 58a limits the insertion depth of the needle 46 within the first molded hub portion 42."

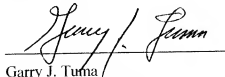
These claims should be allowable for the same reasons as their respective independent claims 1 and 10.

Moreover, Kruck does not show or suggest such a needle stop. To the contrary, Kruck's needle 24 extends completely through hollow key member 48 ( $\approx$  the first hub portion) and sealing membrane 18 into syringe barrel 12. Thus, these claims should be allowable for that reason as well.

Conclusion

The foregoing demonstrates that claims 1-7, 9-16, 18-21, 28, and 29 are allowable. Therefore, subject to the disposition of withdrawn claims 22-27, this application is in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,



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